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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,916	10/06/2003	Nader Najafi	IB-10	2944

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EXAMINER	
PATEL, NATASHA	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,916	NAJAFI ET AL.	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6 January 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Copy the claim language pertaining to the treatment system of Claim 33 into the specification.

Claim Rejections - 35 USC § 112

2. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the term "but not limited to" is indefinite because it does not point out whether the claim is limited to the listed items or not.

Claim Rejections - 35 USC § 101

3. The claimed invention is directed to non-statutory subject matter. Claims 9, 24, and 30 claim nonstatutory subject matter (i.e. the body). It is suggested that Claim 9 be rephrased to say that the sensing devices are *adapted to be* located within said conduit. Claims 24 and 30 should be rephrased in a similar fashion.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

5. Claims 1-5, 7, 9-12, 15-31, 36, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Govari et al. (US Patent 6,636,769).

6. Regarding Claim 1, Govari discloses a system for monitoring one or more physiological parameters (see col. 2, lines 28-32) for diagnosis of cardiac conduit condition in patients heart disease, said system comprising:

One or more implantable sensing devices (see col. 2, lines 34-36), said sensing device comprising of at least one inductor coil (see col. 6, lines 24-25) and at least one sensor (sensor 50), with optional electronic components (see col. 7, lines 3-15);

A non-implantable readout device (see col. 2, lines 43-44), said readout device comprising of at least one inductor coil (see col.2, lines 59-62) allowing electromagnetic telecommunication (see col. 2, lines 48-49) and electromagnetic wireless powering (see col. 2, lines 49-51).

7. Regarding Claim 2, Govari discloses that the implantable sensing device comprises of at least one capacitive sensor (see col. 6, lines 31-32).

8. Regarding Claim 3, Govari discloses that the implantable sensing device includes a battery (see col. 12, lines 28-31).

9. Regarding Claim 4, Govari discloses that the battery is rechargeable using wireless means (see col. 9, lines 63-67). Because the sensor is a low power battery and the reader/charger charges the sensor wirelessly, the battery is essentially being recharged wirelessly.

10. Regarding Claim 5, Govari discloses that the physiological parameters include pressure (see col. 4, lines 9-11).

11. Regarding Claim 7, Govari discloses that one or more sensing devices are measuring one or more of the following pressures: left atrium, right atrium (see col. 10, lines 50-60).

12. Regarding Claims 9-11, statements relating to where the apparatus is located within the body fail to saliently distinguish over the Govari reference since Govari's invention is capable of being placed in these locations (see col. 11, lines 42-47). Thus, these claims stating intended use or location for the apparatus are met by the Govari reference.

13. Regarding Claim 12, Govari discloses that the sensing device is used for indication of occlusion (see col. 6, lines 24-28). Any implantable system with a sensor is *capable* of indicating occlusion. Since Govari's invention is capable or performing the intended use of indicating occlusion, then it meets the claim (*In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962)). Statements of intended use in an apparatus claim do not distinguish over the prior art apparatus.

14. Regarding Claim 15, Govari discloses that the implantable sensing device is used for estimation of time-to-failure within said conduit. Any implantable system with a sensor is *capable* of being used for estimation of time-to-failure. (). If a prior art structure

15. Regarding Claim 16, Govari discloses that the implantable sensing devices are used for the assessment of stenosis (see stenosis 22, col. 12, lines 54-64). Any implantable system with a sensor is *capable* of being used to assess stenosis.

16. Regarding Claim 17, Govari discloses a passive scheme (see col. 8, line 41).

17. Regarding Claim 18, Govari discloses measuring pressure (see col. 4, lines 9-11).

18. Regarding Claim 19, Govari discloses that the system is used for early diagnosis of congenital heart disease and related conditions (see col. 10, lines 1-17).

19. Regarding Claim 20, Govari discloses that the readout device is capable of providing portable or ambulatory monitoring/diagnostic systems (see Figure 8). The examiner believes since the readout device is small and lightweight, it is capable of being portable.

20. Regarding Claim 21, Govari discloses that the implantable device is implanted using a minimally invasive outpatient technique (see col. 12, lines 12-15).

21. Regarding Claim 22, Govari discloses that a catheter delivery method is used to implant the implantable sensing device (see col. 11, lines 2-5).

22. Regarding Claim 23, Govaris discloses that the implantable sensing device uses anchoring mechanisms including a septal occluder device (see col. 12, lines 2-5).

23. Regarding Claim 24, Govaris discloses that the anchoring mechanism is part of the conduit (see col. 6, lines 45-49). The examiner considers that the anchoring legs 64 become part of the conduit because they curve into the tissue to which it is anchoring the sensor.

24. Regarding Claims 25 and 26, Govaris discloses that the anchoring mechanism utilizes an anchor that passes through the atrial septum wall and opens on one or both sides of the septal wall, clamping said implantable device to the wall (see Figure 11). The anchoring legs 64 are on both sides of the septum wall and the sensor 5 is clamped

to the wall. Furthermore, the sensor is clamped in place at the fossa ovalis 407, which is in the atrial septum.

25. Regarding Claim 27, Govaris discloses that the anchoring method is similar to anchoring of septum occluder devices, wherein two umbrella-shaped anchors (64) are on each side, which anchor the sensing device (see Figure 11).

26. Regarding Claim 28, Govaris discloses that the larger portion of said implantable sensing device is located in the right side of the heart and the smaller portion of said implantable sensing device is located in the left side (see Figures 8 and 11) and includes at minimum one sensor (see col. 12, lines 59-66). The examiner considers that the portion of the device with the antenna is smaller than the portion of the device with the electrical components in housing 52 (Figure 8). Furthermore, the housing is in the right side of the heart and the antenna is in the left side of the heart as shown in Figure 11, which is just a closer view of the septum in Figure 10. Although Govaris does not disclose that the sensor is arranged in this manner to minimize thrombogenicity, the examiner considers this part of the claim to be functional language. The sensor disclosed by Govaris is capable of minimizing thrombogenicity if all it requires is the setup described above.

27. Regarding Claim 29, Govaris discloses that the anchoring mechanism is a helical screw (see Figure 3 and col. 3, lines 28-34).

28. Regarding Claim 30, Govaris discloses that the anchoring mechanism is a tine (see col. 6, lines 59-65). The examiner considers that barbs are the same as tines. Furthermore, barbs are *capable* of catching on a tribeculated area of the heart.

29. Regarding Claim 31, Govaris discloses that the anchoring mechanism is made from nitinol (see col. 6, lines 43-45).

30. Regarding Claims 36 and 38, Govari discloses that the cardiac conduit (left atrium) includes a valve (see aortic valve, Figure 10). Furthermore, any diagnostic system is considered an "open-loop" system because the loop has not been "closed" with treatment. Finally, "for control of said valve" is a statement of intended use and does not patentably distinguish over the Govari reference.

31. Claims 1, 6, 13-14, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Govari et al. (US Patent 6,053,873).

32. Regarding Claim 1, Govari discloses a system for monitoring one or more physiological parameters (see col. 3, lines 14-18) for diagnosis of cardiac conduit condition in patients heart disease, said system comprising:

One or more implantable sensing devices (see col. 3, lines 28-30), said sensing device comprising of at least one inductor coil (see coil 94, col. 14, lines 56-63) and at least one sensor (sensor 84), with optional electronic components (circuitry 26);

A non-implantable readout device (see receiver, col. 3, lines 14-18), said readout device comprising of at least one inductor coil (see col. 4, lines 58-60) allowing electromagnetic telecommunication (see col. 4 line 60 - col.5, line 3) and electromagnetic wireless powering (see col. 3, lines 35-43).

33. Regarding Claim 6, Govari discloses that the physiological parameters include pressure gradient (see col. 14, lines 29-36). The examiner considers that since pressure

gradient is the change in pressure over a given distance, then the variations in pressure along the length of the stent is the pressure gradient.

34. Regarding Claim 13, Govari discloses two sensing devices are used for locating occlusion (see col. 6, lines 24-28). The examiner considers that the multiple pairs of electrodes allow for locating the occlusion along the stent because if there is a lower impedance between the third pair of electrodes, for example, then the occlusion is also between the third pair of electrodes.

35. Regarding Claim 14, Govari discloses two implantable sensing devices for the measurement of flow rates (see col. 10, lines 51-59).

36. Regarding Claim 32, Govaris discloses that the implantable sensing mechanism is augmented with one or more actuators including electrodes (see Claim 2).

Claim Rejections - 35 USC § 103

37. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

38. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Govari et al. (US Patent 6,636,769).

39. Regarding Claim 8, Govari discloses that the system is sensitized to detect changes in signal (see col. 8, lines 65-68). Govari further discloses the gathering of multiple readings every second (see col. 12, lines 40-44). Govari does not disclose detecting the rate of change in the signals. However, the particular parameter calculated

simply depends upon the type of cardiac condition associated with the patient. In addition, the applicant does not give any criticality to the calculation of dp/dt. Since Govari requires some type of calculation for detecting change, the calculation of dp/dt would have been an obvious choice by anyone looking to detect a change in pressure to determine whether or not there are any problems in the cardiac conduit.

40. Claims 34 and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Govari et al. (US Patent 6,636,769) in view of Weissman et al. (US Patent 6,092,530).

41. Regarding Claims 34 and 35, Govaris discloses that a portion of said implantable sensing device is coated with one or more layers of thin coatings (see col. 4, lines 18-20). Govaris does not disclose that the coating is made of any of the materials listed in Claim 35. However, it is well-known and common to coat implanted devices to prevent thrombosis. Weissman is cited for coating a sensor with a polymer (see col. 6, line 65- col. 7, line 6). PTFE is a common polymer used in medical devices. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Govari's nonthrombogenic agent into Weissman's polymer to coat the sensor because it improves hemocompatibility and reduces thrombogenesis.

42. Claims 33 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawlak et al. (US Patent 5,135,538) in view of Govari et al. (US Patent 6,636,769).

43. Regarding Claims 33 and 37, Pawlak discloses a closed-loop medical treatment system that controls a valve dependent on pressure changes (see col. 8, line 64- col. 9, line 17). Pawlak does not elaborate on the structure of the mechanism used to detect these changes. Govari discloses the diagnosis of a condition of the heart (see col. 10,

lines 2-6) by detecting changes with a pressure sensor (see col. 4, lines 9-11) having specific structure. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to treat a condition of the heart in a manner described by Pawlak using the pressure sensor disclosed by Govari because the sensor is beneficial to providing the diagnosis necessary for determining the treatment. Finally, 'for control of said valve' is considered a statement of intended use and therefore does not patentably distinguish over the prior art.

Conclusion

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

46. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NNP
5/1/06

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